REMARKS

The Examiner has objected to Figures 4-8 for the low quality of images contained therein. Applicants hereby submit replacement sheets for these figures, and respectfully request the Examiner to withdraw this objection.

Claims 58, 60, 62, 63, 69, 72-91, 93, 95, 96, 98 and 99 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 2-8 and 10 of copending Application No. 10/551,352. Further, these claims stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 2, 18-20, 26, 27, 30, 33-38 and 40 of copending Application No. 11/578,711.

Applicants acknowledge the above provisional rejections. However, since these rejections are only provisional in nature, applicants are not required to take any further action at this time.

Further, applicants note that this application is the earlier-filed application with respect to co-pending Application Nos. 10/551,352 and 11/578,711. Accordingly, pursuant to MPEP 804(I)(B)(1), applicants respectfully request the Examiner to issue this application without requiring terminal disclaimers directed to those copending applications should the claims of this application be found allowable prior to claims of those applications.

Claims 58, 60, 62, 63, 69, 72-91, 93, 95, 96, 98 and 99 stand rejected under 35 USC 112, first paragraph, for lack of enablement. Applicants respectfully traverse this rejection.

First, the Examiner alleges that the specification does not enable those skilled in the art to make and use the claimed invention. Specifically, the Examiner alleges that the objective of the claimed invention is "diagnosing or correlating developed prostate cancer with the down expression of protein inhibin" (Action, page 3, lines 29-30; Emphasis added). Further, the Examiner alleges that, because co-inventor Risbridger's recent publication of 2004 ("Re-Evaluation of Inhibin α Subunit as a Tumor Suppressor in Prostate Cancer," hereinafter "Risbridger") indicates that certain progression of prostate cancer might not exhibit down-regulation of inhibin, there may be limited

instances in which the claimed screening method not detect the presence of cancer. The Examiner further equates this possibility with lack of enablement of the claimed screening method, alleging that the claimed invention is enabled only if there is a complete correlation between the down regulation of inhibin and the presence and absence of prostate cancer.

As explained during the interview with applicants' representatives, in the presence of Supervisory Examiner Shanon Foley, on April 23, 2007, claims 58, 60-63, 69, 72-93, 95, 96, 98 and 99 are directed to "a method of screening" a mammal or a human for prostate cancer, in which the down-regulation of inhibin protein level is "indicative" of having prostate cancer. In other words, this screening method would allow, for example, a health professional to discover prostate cancer in a patient. During the interview, the Examiners had a discussion regarding this point. Examiner Foley explained that it is highly relevant that the claims made reference to the down regulation of inhibin as being "indicative of" having prostate cancer because the down-regulation of inhibin has been a consistent indication of the presence of prostate cancer. That is not equivalent to asserting, for example, that the method would affirm with 100% accuracy the absence of cancer, or that the lack of down-regulation of inhibin would correlate to the absence of cancer, as the Examiner appears to now be asserting. In fact, the absence of cancer cannot be affirmed by most available screening methods, and that is not what the pending claims recite.

For example, while X-ray radiology is a useful screening method for cancer, it may nevertheless fail to discover certain cancers—i.e. cancers in early stage, in certain locations of the body, or having tumors of certain size. Most cancer screening methods cannot positively affirm the absence of cancer with 100% accuracy. Applicants do not assert to have discovered a method to affirm the absence of prostate cancer, and the claims do not recite a method of affirming the absence of prostate cancer with 100% certainty. The claims recite that the down-regulation of inhibin is indicative of having prostate cancer, and the down-regulation of inhibin has been a persistent indicator of the presence of prostate cancer as claimed. In addition, as applicants explain below, the

Examiner has not cited a reference that illustrates a conflicting finding. While ideally it would be good to develop a screening method that verifies the presence and the absence of cancers with 100% accuracy, a screening method that comes short of that perfection can nevertheless be extremely valuable and are used by health professionals everyday.

Further, the claimed screening methods are not rendered "not enabled" simply because the screening method cannot affirm with 100% accuracy the absence of cancer. To satisfy the enablement requirement, the specification must enable one of skill in the pertinent art to make and use the claimed invention. That is to say, that the specification when combined with the information known in the art should be sufficient to allow one of skill in the art to practice the invention without undue experimentation. The specification enables those skilled in the art to perform the recited steps of the claimed screening methods, i.e. by screening for the down regulation of inhibin protein level by taking a sample and determining whether the inhibin protein level is abnormal. The tests set out in the specification are extremely straight forward to perform and reliable in terms of the results they produce. Further, the specification provides working examples that demonstrate that the methods disclosed in the specification are capable of screening for the presence of prostate cancer. While the working examples may not be as extensive as those submitted to the FDA, for example, the specification only need to enable those skilled in the art to make and use the invention, not to provide a percent accuracy for the claimed screening method. Accordingly, the claimed screening method are enabled by the specification, and this rejection should be withdrawn.

Secondly, the Examiner alleges that the state of the art does not indicate a clear correlation between the up and/or down regulation of inhibin with respect to prostate cancer (Action, page 4, line 13-page 5, line 15). The Examiner arrives at this erroneous conclusion by relying heavily on the abstract of Garde (Abstract of Cancer Lett. Vol 78, page 11-7, 1994; hereinafter "Garde"), the abstract of Zhang (Abstract of Hum Pathol vol 30 page 168-72, 1999; hereinafter "Zhang"), and an

article by Schaik (British Journal of Cancer, col 82, pages 112-117, 200). Having concluded that these references do not show a correlation between the down regulation of inhibin and the presence of prostate cancer, the Examiner asserts that the claimed method is merely an interesting invitation for further research and not enabled, thus ignoring the scientific merits of applicants' research of the last decade (Action, page 4, line 13-page 5, line 15).

Applicants respectfully note that the Examiner's reliance on Garde and Zhang is misplaced. The Examiner has misunderstood Garde and Zhang, and thus has incorrectly concluded that the down-regulation of inhibin is not indicative of the presence of prostate cancer. However, Garde and Zhang concern prostatic inhibin-like peptide (hereinafter "PIP"), not "inhibin" as disclosed and claimed in the context of this application (*see* Specification, page 1, line 25-page 2, line 25). As applicants have already repetitively explained to the Office dating back from 2002, PIP and "inhibin" are two different molecules, and those skilled in the art readily understand that these two are not the same.

For example, in the Action dated March 26, 2002, Examiner Nickol has erroneously assumed that PIP mentioned in Tenia et al., yet another reference, to be inhibin (Action, page 5, lin2 14-20). Thus, in the response dated September 26, 2002, applicants pointed out that PIP, which is also known as PSP94 or β-microseminoprotein, is a molecule having no sequence homology to inhibin and does not belong to the TGF-β superfamily, to which inhibin belongs (Response, page 5, lines 10-17). In addition, with the response filed on March 25, 2004, applicants submitted a copy of an article by Gordon *et al.* (1997) Biol. Reproduction 36(4):829-35, which explains that these molecules are not the same. Those skilled in the art are aware that new proteins are often initially named for their activity and not necessarily for their structure. A person of ordinary skill in the art would not have confused PIP mentioned in Garde and Zhang with inhibin of the claimed invention. Thus, the teachings of Garde and Zhang are irrelevant to the claimed invention, and the increase or decrease of the level of PIP or the lack of its correlation with prostate cancer do not support the

Examiner's conclusion that the state of arts appears to suggest the claimed method would not be able to screen for the presence of prostate cancer. As explained during the interview and explained above, the results presented by Schaik and the recent publication by Risbridger are completely consistent with the disclosure of this application in that the down-regulation of inhibin has been a persistent indicator for having prostate cancer as claimed. Thus, applicants respectfully request the Examiner to withdraw this lack of enablement rejection for this additional reason.

Finally, the Examiner points out that the claim language "developed cancer" is not defined in the specification (Action, page 3, lines 29-21). Applicants take this opportunity to note that the claim language "developed prostate cancer" means simply "to develop cancer." This is a common English expression which does not necessitate a definition.

In view of the above, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Attorney Docket No. **229752000800**.

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Respectfully submitted,

By _____

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